



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,207	03/02/2004	Xing Pei	A04P1020	4191
36802	7590	12/11/2006	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			WU, EUGENE TONG	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/792,207

Applicant(s)

PEI ET AL.

Examiner

Eugene T. Wu

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/02/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 2-4, 10, 11, 19, 21, and 22 objected to because of the following informalities:
 - a. Claims 2-4, 10, 11: These claims use the limitation "the R wave", which lacks antecedent basis in the claims, because claim 1 recites "a far-field R wave". For example, claim 2 appears to be further defining "the R wave" to be a "far field R wave", but the R wave was already defined to be far-field in claim 1. Also, claim 3 recites "the R wave" sensed via the ventricular channel, which is a near-field R wave and not a far-field R wave.
 - b. Claim 19, line 3: "a minimum pacing" should be "a maximum pacing".
 - c. Claims 21, 22: "the blanking means" and also "the blanking interval" lack antecedent basis in the claims. Claims 21 and 22 should claim dependency from claim 20, not claim 19. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, it is unclear whether the blanking period recited corresponds to the minimum RA interval 140 or the T-wave blanking/revised refractory period 138. The minimum RA interval 140 is shown to begin with detection of the R-wave (Figure 3), whereas the T-wave blanking/revised refractory period 138 is disclosed to begin after the R-wave detection (Paragraphs 62, 70). However, only the T-wave blanking/revised refractory period 138 is disclosed to act as a detector blanking

Art Unit: 3766

period (Paragraphs 62, 70, 72; see Figure 4: 174). Does the minimum RA interval serve blanking purposes as well? Or, does the T-wave blanking period begin essentially with detection of the R-wave? If Applicant intends to claim the T-wave blanking period, it is suggested to change "beginning with detection of the R wave" to "beginning after detection of the R wave", in accordance with what is disclosed in the specification (Paragraphs 62, 70).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 12, 13, 18, and 19 rejected under 35 U.S.C. 102(b) as being anticipated by Esler (US 6,128,529).

Regarding claims 12 and 19, Esler discloses the same invention substantially as claimed, including detecting an atrial activation 300 (Col. 6, lines 51-56; Figure 3), detecting an R wave 310, determining the time remaining in the AV interval 315 and adding the time to the VA interval 320 (Col. 7, lines 1-18), which is considered equivalent to Applicant's determining minimum RA interval, and imposing the minimum RA interval, as shown in Figure 5 (Default VA interval is 500 ms, after Vpulse 552. Lengthened VA interval of 650 ms, after Vpulse 556, is imposed to maintain 800 ms A-A interval; see also Col. 9, lines 1-35).

Regarding claim 13, Esler discloses sensing the R wave with a ventricular electrode configuration (Figure 2).

Regarding claim 18, Esler discloses determining the RA interval based upon pacing rate (Col. 9, lines 53-67; Col. 10, lines 5-10; Col. 11, lines 57-67; Figures 6 and 7).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. In light of the objections above, the Office is regarding claims 21 and 22 as depending from claim 20, to match the dependency pattern of claims 1, 4, and 5.

9. In light of the 112 rejection above, the Office is interpreting claim 11 to be the T-wave blanking period 138.

10. Claims 1-5, 9, 10, 12, 14-16, and 19-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Sloman (US 6,101,416), in view of Esler (US 6,128,529).

Regarding claims 1, 2, 12, 14, and 19, Sloman discloses the same invention substantially as claimed, including detecting an atrial activation (Col. 7, lines 13-39), and detecting a far-field R wave (Col. 4, lines 35-50). Sloman does not disclose determining and imposing a minimum RA interval.

Art Unit: 3766

However, Esler teaches determining the time remaining in the AV interval 315 (Figure 3) and adding the time to the VA interval 320 (Col. 7, lines 1-18), which is considered equivalent to Applicant's determining minimum RA interval, and imposing the minimum RA interval, as shown in Figure 5 (Default VA interval is 500 ms, after Vpulse 552. Lengthened VA interval of 650 ms, after Vpulse 556, is imposed to maintain 800 ms A-A interval; see also Col. 9, lines 1-35), for the purpose of reducing the risk of delivering inappropriate anti-tachyarrhythmia therapy. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the determining and imposing of a minimum RA interval of Esler with the device of Sloman for the purpose of reducing the risk of delivering inappropriate anti-tachyarrhythmia therapy.

Regarding claim 3, Sloman further discloses sensing the R wave through a ventricular channel (Figure 1).

Regarding claims 4, 15, and 20, Sloman further discloses a window delay between the delivery of the atrial stimulation pulse and generation of the far-field signal, which is considered equivalent to Applicant's blanking interval commencing with detection of the atrial activation and ending prior to detection of the R wave (Col. 9, lines 8-29).

Regarding claims 5, 16, and 21, Sloman further discloses dynamically varying the blanking interval (Col. 6, lines 9-36; Figures 4 and 5).

Regarding claim 9, Sloman does not disclose a rate responsive adjustment to the RA interval. However, Esler further discloses determining the RA interval based upon pacing rate (Col. 9, lines 53-67; Col. 10, lines 5-10; Col. 11, lines 57-67; Figures 6 and 7), for the purpose of responding to physiological indications that heart rate should be varied. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to further include the

Art Unit: 3766

determining the RA interval based upon pacing rate of Esler with the device of Sloman for the purpose of responding to physiological indications that heart rate should be varied.

Regarding claim 10, Sloman further discloses a morphology detector (Col. 5, lines 46-64; Col. 9, lines 30-43; Figure 3).

11. Claims 6, 7, and 22 rejected under 35 U.S.C. 103(a) as being unpatentable over Sloman (US 6,101,416) and Esler (US 6,128,529) as applied to claims 4 and 20 above, and further in view of Sholder (US 5,334,220).

Sloman and Esler do not disclose a first blanking period duration responsive to intrinsic atrial activity shorter than a second blanking period duration responsive to paced atrial activity. However, Sholder teaches using a PV interval that is shorter than an AV interval, in order to account for the latency time between applying an A-pulse and the atrial tissue responding with depolarization (Col. 8, lines 28-33). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the PV interval shorter than the AV interval of Sholder with the modified device of Sloman and Esler, in order to account for the latency time between applying an A-pulse and the atrial tissue responding with depolarization.

12. Claims 8, 11, 17, and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Sloman (US 6,101,416) and Esler (US 6,128,529) as applied to claims 1, 12, and 19 above, and further in view of McClure et al. (US 6,711,438).

Sloman and Esler do not disclose a refractory period or a revised refractory period. However, McClure shows a PVARP and PVAB, which are considered equivalents of Applicant's refractory period following detection of atrial activation, and also shows a T-wave blanking interval,

Art Unit: 3766

which is considered equivalent to Applicant's revised refractory period, for the purpose of determining the true atrial rate (Col. 4, lines 8-38, 41-53; Figure 5). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the refractory and revised refractory periods of McClure with the modified device of Sloman and Esler, in order to determine the true atrial rate.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Florio (US 6,477,416) shows detecting far field R waves.
- b. Stoop (US 5,999,853) shows detecting far field R waves.
- c. Reuter (US 4,523,593) shows adjusting the VA interval to maintain constant A-A interval.
- d. Weinberg (US 6,539,259) shows a T-wave blanking period.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eugene T. Wu whose telephone number is (571) 272-3109. The examiner can normally be reached on M-F: 9 AM - 5 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ETW
12/06/2006


Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766